PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: AD

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	13.07.2004
Applicant's or agent's file reference: 15228-16pct-1 ✓	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA 03/00604	30.04.2003	30.04.2002

Applicant: ORTHOSOFT INC. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 15228-16pct-1	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/CA 03/00604	International filing date *(day/month/year)* 30.04.2003	Priority date *(day/month/year)* 30.04.2002
International Patent Classification (IPC) or both national classification and IPC A61B19/00		
Applicant ORTHOSOFT INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
25.11.2003	13.07.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Held, G Telephone No. +49 89 2399-2248

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA 03/00604

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1, 3-11	as originally filed
2, 2a	received on 04.06.2004 with letter of 04.06.2004

Claims, Numbers

1-13, 27	as originally filed
14-26	received on 04.06.2004 with letter of 04.06.2004

Drawings, Sheets

1/11-11/11	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-14

   because:

   ☒ the said international application, or the said claims Nos. 1-14 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 1-14

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/ or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	15-27
	No:	Claims	
Inventive step (IS)	Yes:	Claims	15-27
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	15-27
	No:	Claims	

2. Citations and explanations

see separate sheet

1. Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The claims 1-14 concern a method for treatment of the human body (surgery). However, according to Rule 67.1(iv) PCT, an International Preliminary Examining Authority is not required to carry out international preliminary examination based on such method claims.

2. Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: WO-A-99/60 939
D2: DE-A-10 031 887

2.1 The document D2 discloses (the references in parentheses applying to this document):
The document D2 is regarded as being the closest prior art to the subject-matter of independent claim 15 and shows the following features thereof (the references in parentheses applying to this document):

A system for determining the distal cut thickness and posterior cut thickness for a femur in a knee replacement operation comprising a computer memory, a measurement module, a computing module and an output device (column 3, line 40 - column 4, line 67).

The essential differentiating feature of the subject-matter defined in the present independent claim 15 in comparison with the disclosure of document D2 is that the computing module is adapted to calculate a distal cut thickness and a posterior cut thickness by **taking the data of the measured extension gap and the flexion gap into account.**
The problem to be solved is to optimize the placement of an implant in knee replacement operations. None of the available prior art documents gives any hint to

measure the extension and flexion gap in order to determine the distal cut thickness and the posterior cut thickness. Therefore, the subject-matter defined in claim 15 is considered to fulfill the requirements of Article 33(2) and (3).

2.2 Claims 16 - 27 are dependent on claim 15 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

3. The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

14. A method as claimed in claim 13, wherein said registering said cut comprises creating a plane along said tibial cut on said reference coordinate system and said determining a most posterior point of a reference comprises raising said plane on said tibial cut until said most posterior point of said femur is reached.

15. A system for determining a distal cut thickness and posterior cut thickness for a femur in a knee replacement operation, said system comprising:

a computer memory ~~for~~ adapted to holding data relating to size and shape of at least one femoral implant;

a measurement module ~~for~~ adapted to measuring an extension gap between said femur and said tibia while in extension and a flexion gap between said femur and said tibia while in flexion and generating measurement data;

a computing module adapted to receiving said measurement data and to calculating a distal cut thickness and a posterior cut thickness for said femur using said extension gap and said flexion gap and taking into account a distal thickness and posterior thickness of a femoral implant; and

an output device ~~for~~ adapted to outputting said measurement data and calculated data calculated by said computing module.

16. A system as claimed in claim 15, wherein said measurement module comprises:

a registration module ~~for~~ adapted to registering said femur and a tibia to a reference coordinate system for display on said output device; and

a tracking device ~~for~~ adapted to tracking motion of said femur and said tibia in said reference coordinate system.

17. A system as claimed in claims 15 or 16, wherein said computing module fixes said posterior cut thickness, said distal thickness, and said posterior thickness and calculates said distal cut thickness.

18. A system as claimed in any one of claims 15 to 17, wherein said computing module is adapted to calculates said distal cut thickness and said posterior cut thickness such that a post-cut gap from said tibia to said femur is equal in extension and in

flexion.

19. A system as claimed in any one of claims 15 to 18, wherein said computing module is adapted to considers a user-input minimum cut thickness to calculate said posterior cut thickness and said distal cut thickness.

20. A system as claimed in claim 15, wherein said computing module is adapted to adds said flexion gap measurement to a femoral implant size constant and subtracts said extension gap measurement to calculate said distal cut thickness.

21. A system as claimed in claim 20, wherein said femoral implant size constant takes into account a distal thickness of said femoral implant.

22. A system as claimed in claim 21, wherein said femoral implant size constant takes into account a posterior thickness of said femoral implant.

23. A system as claimed in claim 15, wherein said measurement module is adapted to measures an actual mechanical axis of said femur and said tibia and said computing module is adapted to determines an adjustment to be performed on soft tissues of said knee to obtain soft tissue balancing of said knee such that said knee is substantially aligned with a desired mechanical axis.

24. A system as claimed in claim 23, wherein said output device is adapted to displays said desired mechanical axis superimposed on images corresponding to said femur and tibia.

25. A system as claimed in claim 16, wherein said registration module comprises a digitizer to register a surface of said femur and said tibia to said reference coordinate system.

26. A system as claimed in claim 25, wherein said registration module comprises markers for attachment to said femur and said tibia.

Traditionally, this task is performed manually by the surgeon and is dependent on the surgeon's expertise.

Therefore, it would be advantageous to design a system which would automatically determine where the cuts on a bone were to be made and to a precision not afforded by even the most skilled surgeon.

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SUMMARY OF THE INVENTION

An object of the present invention is to optimize the placement of an implant or prosthesis in knee replacement operations in order to extend the lifetime of the implant to its maximum.

According to a first broad aspect of the present invention, there is provided a method for determining a distal cut thickness and posterior cut thickness for a femur in a knee replacement operation, the method comprising: performing a tibial cut on a tibia; performing soft tissue balancing based on a desired limb alignment; measuring an extension gap between the femur and the tibial cut while in extension; measuring a flexion gap between the femur and the tibial cut while in flexion; calculating a distal cut thickness and a posterior cut thickness for the femur using the extension gap and the flexion gap and taking into account a distal thickness and posterior thickness of a femoral implant; and performing a femoral cut according to the distal cut thickness and the posterior cut thickness.

Preferably, the distal cut thickness and the posterior cut thickness are calculated such that a post-cut gap from the tibia to the femur is equal in extension and in flexion, i.e. the gaps are balanced. Also preferably, performing a tibial cut comprises obtaining a tibial cut that is substantially perpendicular to a mechanical axis of said limb and the femoral cut is then performed such that it is parallel to the tibial cut. This way, the gaps are rectangular.

According to a second broad aspect of the present invention, there is provided a system for determining a distal cut thickness and posterior cut thickness for a femur in a knee replacement operation, the system comprising: a computer memory for holding data relating to size and shape of at least one tibial implant and at least one femoral implant; a measurement module, for measuring an extension gap between the femur and the tibia while in extension and a flexion gap between the femur and the tibia while in flexion and generating measurement

Document WO 99/60939 describes a computer-assisted surgical system comprising a computer including three-dimensional models of anatomical structures and a user interface including a position sensing system to register in real-time the relative positions of the anatomical structures of interest and of a surgical tool. Interactions between the tool and the anatomical structure are displayed on a monitor using the three-dimensional models allowing the surgeon to visualize the interaction between the tool and the anatomical structures anytime during the surgical procedure.